Produce Safety Rule: Enforcement Policy for Entities Growing, Harvesting, Packing, or Holding Hops, Wine Grapes, Pulse Crops, and Almonds

Guidance for Industry

You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2019-D-1266 listed in the notice of availability published in the *Federal Register*.

For questions regarding this document, contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1700.

U.S. Department of Health and Human Services
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I. Introduction

The purpose of this document is to state the intent of the Food and Drug Administration (FDA, we, or the Agency) not to enforce the requirements of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption regulation (21 CFR Part 112) as they apply to entities growing, harvesting, packing and holding certain commodities.

We are issuing this guidance consistent with our good guidance practices (GGP) regulation (21 CFR 10.115). This guidance is immediately effective because FDA has determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

In this guidance, pronouns such as "you" refer to entities that are covered by this guidance.

II. Background

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353) directs the FDA to better protect public health by, among other things, adopting a modern, preventive, and risk-based approach to food safety. The final rule, "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (the Produce Safety Rule), published on November 27, 2015, established science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption. These

requirements are codified in 21 CFR part 112. The Produce Safety Rule is one of the seven foundational regulations that we issued as part of our implementation of FSMA.

Produce is subject to the Produce Safety Rule unless it is "not covered" or is eligible for an exemption. Produce is not covered by the Produce Safety Rule if it is:

- Rarely consumed raw (§ 112.2(a)(1));
- Produced for personal or on-farm consumption (§ 112.2(a)(2)); or
- Not a raw agricultural commodity (§ 112.2(a)(3)).

"Rarely consumed raw" (RCR) produce refers to commodities that FDA determined are almost always eaten only after being cooked, which are included in an exhaustive list at 21 CFR 112.2(a)(1) (the RCR list). FDA's classification of produce as "rarely consumed raw" was based on consumption patterns reported in the National Health and Nutritional Examination Survey (NHANES), which is the most comprehensive and robust, nationally representative dataset currently available on dietary intake in the United States. To be included on the RCR list, consumption patterns for a commodity had to meet certain criteria. First, the commodity had to be consumed uncooked by less than 0.1 percent of the United States population; and second, the commodity had to be consumed uncooked on less than 0.1 percent of eating occasions. If a commodity satisfied the first two criteria we then considered a third criterion: that consumption in any form – raw, processed, or other – was reported by at least 1 percent of a weighted number of survey respondents. Commodities that failed to satisfy all three of the criteria were not included on the RCR list. However, in the preamble to the Produce Safety Rule, we stated that we intended to consider updating the RCR list in the future as appropriate, and we encouraged stakeholders who have relevant information to submit data that are sufficiently robust and representative to allow FDA to draw scientifically valid conclusions.

Produce otherwise covered by the Produce Safety Rule is eligible for exemption from most of its requirements if the produce is commercially processed to adequately reduce the presence of microorganisms of public health significance, and certain recordkeeping and documentation requirements are satisfied ("the commercial processing exemption," 21 CFR 112.2(b)).

In the final rule, we announced staggered compliance dates, based on business size. Sprout growers are subject to earlier dates, but for all other growers covered by the Produce Safety Rule, the compliance date for very small businesses is January 27, 2020; for small businesses it is January 28, 2019; and for all other businesses it is January 26, 2018.[1] However, based in part on feedback from stakeholders that more time was necessary to ensure growers have the training and information needed to comply with the regulations, FDA announced that routine produce safety inspections would not begin until the spring of 2019 (see https://www.fda.gov/NewsEvents/Speeches/ucm575499.htm).

[1] On March 18, 2019, FDA issued a final rule that extends the compliance dates for all of the agricultural water provisions in the Produce Safety Rule (for produce other than sprouts) to 2022-2024, depending on the size of the farm. See 84 FR 9706.

III. Discussion

Following the publication of the final rule, FDA received feedback from some stakeholders that certain covered commodities should be exempt from the requirements of the Produce Safety Rule.

A. Hops

In the final rule, hops were not included on the RCR list because FDA could not conclude that hops are not consumed uncooked in any measurable quantity by most consumers across the United States (see 80 FR 74354 at 74394). However, FDA did note that hops used in the making of beer are eligible for the commercial processing exemption; we said that brewing beer adequately reduces the presence of microorganisms of public health significance through means other than a cook step (e.g., pH, alcohol content, fermentation) (see 80 FR 74354 at 74394).

Following publication of the final rule, FDA received a request from hops growers that hops be exempt from the Produce Safety Rule on the grounds that the beer brewing process is recognized as adequately reducing the presence of microorganisms of public health significance and hops are not used outside of the brewing process (Ref. 1). Our own analysis has led FDA to believe that, given hops' unique circumstances, we should further explore options for potentially exempting the commodity from the Produce Safety Rule. Informed in part by our conclusion in the final rule that hops used in the making of beer receive adequate pathogen reduction, we intend to exercise enforcement discretion for entities growing, harvesting, packing, or holding hops while we explore this topic further and possibly pursue rulemaking.

B. Wine Grapes

In the final rule, wine grapes were not included on the RCR list. Based on the NHANES datasets used to establish the RCR list, the uncooked consumption data available for "grapes, wine and sherry" exceeded the relevant quantitative criteria. In the preamble to the final rule, we noted that we did not have information on specific grape cultivars or varieties that are exclusively grown for use in winemaking to establish a separate category covering only "wine grapes." Additionally, we stated that we were aware that some grape varietals are multi-purpose in use, i.e., used as both wine grapes and table grapes (see 80 FR 74354 at 74395). However, FDA noted that grapes used in the making of wine are eligible for the commercial processing exemption (§ 112.2(b)(1)) and stated that winemaking adequately reduces the presence of microorganism of public health significance through means other than a cook step (e.g., pH, alcohol content, fermentation) (see 80 FR 74354 at 74395).

Following publication of the final rule, FDA received feedback from wine grape growers that only certain grape varietals are used for winemaking and these varietals differ from those marketed as table grapes or for other uses. These wine grape growers also indicated that the growing and harvesting practices differ between wine grape and other grapes (Refs. 2, 3). We also note that in the Consolidated Appropriations Act, 2019, Congress stated: "None of the funds

made available by this or any other Act may be used to enforce the [Produce Safety Rule] with respect to the regulation of the production, distribution, sale, or receipt of grape varietals that are grown, harvested and used solely for wine and receive commercial processing that adequately reduces the presence of microorganisms of public health significance" (Pub. L. 116-6, section 758).

We have continued to study the growing, harvesting, packing, holding, and use of wine grapes and believe that they are a sufficiently distinct commodity – and one that receives adequate pathogen reduction, as discussed in the preamble of the final rule – that we can exercise enforcement discretion for those grape varietals that are grown, harvested, and used solely for wine while we further explore options for potentially exempting this commodity from the Produce Safety Rule.[2]

C. Pulse Crops

Pulses are the dry, edible seeds of plants in the legume family (Ref. 4). The term "pulses" includes only crops harvested solely in dried form and does not include crops harvested green for food, such as green peas or green beans, or crops used mainly for oil extraction (Ref. 4). The Food and Agricultural Organization of the United Nations (FAO) has identified 11 types of pulse crops: dry beans, broad beans, dry peas, chick-peas, cow peas, pigeon peas, lentils, bambara beans, vetches, lupins and pulses NES (not elsewhere specified) (Ref. 5).

In § 112.2(a)(1) of the Produce Safety Regulation, some pulse crops are on the RCR list and are therefore exempt from the regulation (specifically, black beans, great Northern beans, kidney beans, lima beans, navy beans, pinto beans, chickpeas, and lentils), while other pulse crops are not on the RCR list. The general category of "peas" is identified as covered produce in § 112.1(b)(1). We did not differentiate between succulent peas and succulent podded peas (neither of which are pulse crops) and dry peas (which are pulse crops) in § 112.1(b)(1); none of these types of pea met the criteria for "rarely consumed raw." The NHANES consumption data for both succulent peas and succulent podded peas exceeded the relevant quantitative criteria, and therefore succulent peas and succulent podded peas are covered produce under the final rule. We did not include dry peas on the RCR list because they did not meet the third criteria for "rarely consumed raw" due to limited consumption data in NHANES. In addition, cowpea beans (black-eyed peas), a pulse crop, are also specifically listed as covered produce, because they also did not meet the third criteria for "rarely consumed raw" due to limited consumption data (see 80 FR 74354 at 74394). The RCR list is exhaustive, whereas the examples of covered produce are a non-exhaustive list; therefore, any pulse crops that are not listed as "rarely consumed raw" are covered by the Produce Safety rule if they meet the other criteria for coverage (e.g., being a raw agricultural commodity).

FDA has received feedback from pulse growers that all pulse crops should be included in the RCR list, as they are all dried, processed, and cooked prior to consumption (Ref. 6). As we have

[2] We are aware that individual farms might not have sufficient information to determine, on an industry-wide basis, which grape varietals are grown, harvested, and used solely for making wine. At this time, in situations where the individual farm grows, harvests, and uses the varietal solely for making wine, we intend to exercise enforcement discretion with respect to the growing and harvesting of the varietal on that farm.

continued to explore this topic, we have taken note of the fact that succulent peas and dry peas are recognized as distinct commodities in terms of grading – dry peas are graded by the United States Department of Agriculture (USDA) Grain Inspection, Packers and Stockyards Administration (GIPSA) and succulent peas are graded by USDA Agricultural Marketing Service (AMS) (Refs. 7, 8) (note that AMS refers to succulent peas as "fresh" peas). After conducting a review of how pulse crops are grown, harvested, packed, held, and used, we have decided to exercise enforcement discretion for entities growing, harvesting, packing, or holding pulse crops that are not currently classified as "rarely consumed raw" while we explore this topic further and consider pursuing rulemaking to address the unique circumstances of these commodities[3].

D. Almonds

In the final rule, FDA concluded that almonds did not meet the criteria to be considered "rarely consumed raw" because the NHANES analysis did not conclude that less than 0.1% of the population consumed the product uncooked and that the commodity is consumed uncooked on less than 0.1 percent of eating occasions (see 80 FR 74354 at 74392). Following the publication of the final rule, FDA has received input from almond growers and we have conducted our own analysis of the commodity.

As we have continued to explore this topic, we have taken note of the fact that virtually all almonds commercially produced in the United States are grown in California (Refs. 9,10). Under the California Almond Federal Marketing Order (7 CFR Part 981) issued by USDA AMS, all almonds shipped from handlers to locations within the United States, Canada, or Mexico must undergo a treatment for the control of *Salmonella*. Examples of validated treatment processes for almonds under this marketing order are blanching, roasting, steam treatment, and treatment with propylene oxide (Ref. 11).

After conducting a review of how almonds are grown, harvested, packed, held, processed, and used, FDA has decided to exercise enforcement discretion for entities growing, harvesting, packing, or holding almonds while we explore this topic further and consider pursuing rulemaking to address the unique circumstances of this commodity.

IV. Conclusion

We are considering pursuing rulemaking to address the unique circumstances of these commodities. In the meantime, FDA intends to exercise enforcement discretion with respect to the Produce Safety Rule for entities growing, harvesting, packing or holding hops, wine grapes, pulse crops, and almonds. This means that we will not expect entities growing, harvesting,

[3] Pulse crops that are included on the RCR list in the final rule continue to be exempt from the Produce Safety Regulation.

packing, or holding these commodities to meet any of the Produce Safety Regulation requirements with respect to these commodities.

We will consider revising our intent to exercise enforcement discretion if, for example, new information becomes available regarding safety concerns associated with the production and consumption of these commodities. In addition, the statutory prohibition against the introduction or delivery for introduction into interstate commerce of adulterated food (section 301(a) of the FD&C Act (21 U.S.C. 331(a)) continues to apply, regardless of our intent to exercise enforcement discretion with respect to the Produce Safety Rule. For example, under section 402(a)(4) of the FD&C Act (21 U.S.C. 342(a)(4)), a food shall be deemed to be adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health, regardless of whether the food is a commodity for which we intend to exercise enforcement discretion under the Produce Safety Rule.

V. References

Ref. 1: Hop Growers of America Letter to FDA, May 9, 2018 and Hop Growers of America Letter to FDA Hops Administrative Record, August 29, 2018.

Ref. 2: California Wine Growers Letter to Susan Mayne, June 15, 2017.

Ref. 3: Napa Valley Vintners letter to Scott Gottlieb, July 7, 2017.

Ref. 4: http://www.fao.org/pulses-2016/news/news-detail/en/c/337107/, accessed on Feb. 13, 2019.

Ref. 5: http://www.fao.org/es/faodef/fdef04e.htm, accessed on Feb. 13, 2019.

Ref. 6: Treatment of Pulses Under FSMA, A summary from the USA Dry Pea & Lentil Council, April 17, 2018.

Ref. 7: https://www.gipsa.usda.gov/fgis/standards/wholedrypeas.pdf, accessed on Feb. 13, 2019.

Ref. 8: https://www.ams.usda.gov/grades-standards/pea-pods-grades-and-standards, accessed on Feb. 13, 2019.

Ref. 9: Almond Board of California: Almond Industry/Food Safety Overview, Presentation to FDA, May 17, 2017.

Ref. 10: https://downloads.usda.library.cornell.edu/usda-esmis/files/zs25x846c/bc386n064/rr172065h/NoncFruiNu-06-26-2018.pdf, accessed on Feb. 13, 2019.

Ref. 11: http://www.almonds.com/processors/processing-safe-product/pasteurization, accessed on Feb. 13, 2019.